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10/530,128

10/21/2005

Yen Choo

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STEPTOE & JOHNSON LLP  
1330 CONNECTICUT AVENUE, N.W.  
WASHINGTON, DC 20036

EXAMINER

TONGUE, LAKIA J

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

05/17/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                  |  |
|------------------------------|--------------------------------------|----------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/530,128 | <b>Applicant(s)</b><br>CHOO, YEN |  |
|                              | <b>Examiner</b><br>LAKIA J. TONGUE   | <b>Art Unit</b><br>1645          |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 5-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's response filed on January 26, 2010 is acknowledged. Claims 1 and 2 have been amended. Claims 1, 2, and 5-16 are currently pending and under examination.

### ***Rejections Withdrawn***

2. In view of Applicant's arguments, the rejection of claims 1, 2 and 4-16 under 35 U.S.C. 103(a) as being unpatentable over Scholl et al. (U.S.2004/0170965 A1) is withdrawn.

### ***New Grounds of Rejection***

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The rejection of claims 1, 2 and 5-16 under 35 U.S.C. 103(a) as being unpatentable over Nishikawa et al. (Development, 1998; 125: 1747-1757) is maintained for the reasons set forth in the previous office action. Please note, the Examiner unintentionally left claims 9 and 11 out of said rejection. The limitations of claims 9 and 11 are disclosed in said Nishikawa et al. publication. The Examiner regrets this oversight and apologizes for any inconvenience.

Applicant argues that:

1) Nishikawa et al. do not disclose repeating steps (b) and (c) or (d) iteratively, does not disclose a single round of steps (b) and (c) or (d) of claims 1 or 2 nor does Nishikawa et al. disclose the step of sub-dividing one or more of said groups to create a further set of groups of cell units which are subsequently exposes to at least one change of culture conditions.

2) The transfer steps used is directed towards producing cells which are suitable as the starting material for subsequent use.

3) The skilled person viewing Nishikawa would understand that it is the ES cells which must be considered to be the first set of cell units referred to in step (a) of claim 1.

4) Nishikawa does not disclose repeating steps of claim 1 or claim 2 iteratively, nor do they disclose the step of sub-dividing one or more of said groups to create a further set of groups of cell units which are subsequently exposed to at least one change of culture conditions.

5) It is not clear that repeating the step of growing the cell on the coated plate would result in a further effect on the cell and so the skilled person would consider this to be an unnecessary extra step which would simply result in an increased number of samples and thus more work for which there is no motivation.

6) There is no teaching or suggestion in Nishikawa that would lead a person of skill in the art to change the culture conditions under which the iteratively divided cells are grown.

Applicant's arguments have been considered and are deemed non-persuasive.

The rejected claims are drawn to a method for determining the effect of a plurality of culture conditions on a cell comprising the steps of: a) providing a first set of groups of cell units each comprising one or more cells, and exposing said groups to desired culture conditions; b) subdividing one or more of said groups to create a further set of groups of cell units; c) exposing said further groups to at least one change of culture conditions; d) repeating steps (b)-(c) iteratively; and e) assessing the effect on a given cell unit of the culture conditions to which is has been exposed.

With regard to Points 1, 2 and 4, contrary to Applicant's assertion, Nishikawa et al. disclose that CCE ES cells were maintained on Mitomycin C treated embryonic fibroblast layers in Dulbecco modified essential medium containing 15% fetal calf serum. Two weeks before the differentiation induction, one thousand ES cells were transferred to gelatin coated culture dishes. The ES cells were then transferred to each well and incubated in alpha MEM supplemented with 10% FCS (thus meeting the limitation of providing a first set of cell units each comprising one or more cells and exposing said groups to desired culture conditions as recited in step (a); subdividing one or more of said groups to create a further set of groups of cell units as recited in step (b), as well as exposing said further groups to at least one change of culture conditions, which in thus case the Examiner views the change in culture condition to be the difference in the amount of FCS in each medium). Nishikawa et al. disclose that the dishes were coated with gelatin, type I collagen or fibronectin and compared with type IV collagen coated for the ability to support the differentiation of ES cells; thus meeting the limitation of assessing the effect on a given cell unit of the culture conditions to

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which it has been exposed, as recited in step (e). The examiner is viewing the comparison of the cells on different culture conditions and different types of coated dishes to further meet the limitation of assessing the effect on a given cell unit.

Moreover, while Nishikawa et al. do not specifically disclose repeating steps (b)-(c) iteratively; it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Nishikawa et al. by repeating steps (b)-(c) iteratively because repeating the steps creates a highly efficient outcome and allows one to determine which set of conditions would be more effective. The technique of repeating steps iteratively is well within the ordinary capabilities of a person of ordinary skill in the art. Therefore, in view of the teaching of the technique for improvement in other situations, one would have had a reasonable expectation, barring evidence to the contrary, that the method would be effective for determining the effect of a plurality of culture conditions on a cell.

With regard to Point 3, the Examiner concurs; the ES cells should be considered the first set of cell units as referred to in step (a) of claim 1. Said cells were maintained on Mitomycin C treated embryonic fibroblast layers in Dulbecco modified essential medium containing 15% fetal calf serum and then one thousand of those cells were transferred to gelatin coated culture dishes; thus implying a first group of cell units and subdividing said group to create a further group of cell units.

With regard to Point 5, contrary to Applicant's assertion, one of ordinary skill in the art would recognize and perhaps expect that repeating the step of growing the cell on the coated plate would result in a further effect on the cell because the skilled artisan

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would be putting the cell through further steps of subdividing and exposing said cell to a change of culture conditions. A skilled artisan would certainly recognize and expect that the culture of cells would either remain the same or that the cell would undergo some form of change as a result of enduring further steps.

With regard to Point 6, KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR*, 82 USPQ2d at 1396).

As previously presented, Nishikawa et al. disclose a method of analyzing cell cultures. The method involves ES cells which were initially maintained on Mitomycin C treated layers in DMEM. The cells were then transferred to gelatin coated culture dishes to remove fibroblasts. Cells were then transferred (subdivided) to each well of IV collagen-coated 6-well cluster dishes and incubated in alpha MEM supplemented with FCS and 2ME. Moreover, Nishikawa et al. disclose that the cultured cells were harvested with a cell dissociation buffer and analyzed for expression of surface markers. The dishes were coated with gelatin, type I collagen (microcarrier) or fibronectin and compared for the ability to support the differentiation of ES cells. Nishikawa et al. disclose that the atmosphere in the chamber holding the cells was 37°C (see page 748; Cell Culture). Nishikawa et al. disclose preparations of single cell suspensions (see page 1748; Preparation of single cell suspensions from embryos). Lastly, Nishikawa et al. disclose that cell layers were prepared in 96-well cluster dishes.

Nishikawa et al. do not specifically disclose repeating steps (b)-(c) iteratively.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Nishikawa et al. by repeating steps (b)-(c) iteratively because repeating the steps creates a highly efficient outcome and allows one to determine which set of conditions would be more effective.

Moreover, the claim would have been obvious because a particular known technique (i.e. repeating steps iteratively) and the technique for improving a particular method was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations. See the recent Board decision *Ex parte Smith*,--USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR*, 82 USPQ2d at 1396). One would have had a reasonable expectation, barring evidence to the contrary, that the method would be effective for determining the effect of a plurality of culture conditions on a cell.

### ***Conclusion***

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT  
5/11/10

/Robert B Mondesi/  
Supervisory Patent Examiner, Art Unit 1645

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